REMARKS

Status of the Claims

Claims 19-21, 27-33 and 56 were pending prior to the Final Office Action dated October 21, 2002. Claims 51-55 have been withdrawn with traverse. Claims 19 and 56 have been amended (Appendix A). Support for the amendments may be found throughout the specification, for example, at least on page 5 lines 20 to 28 and page 24. Thus, no new matter has been added. For the Examiner's convenience, the pending claims are attached hereto as Appendix B.

Claims 51-55 were withdrawn as being non-elected species

The Action maintains the contention that claims 51-55 should be withdrawn from consideration as being drawn to a non-elected invention since the methods therein are ultimately limited to nucleotides which differ in structure from the nucleotides of the elected methods claims. The Applicants traverse the withdrawal of claims 51-55 and file concurrently a Petition for Reconsideration of Restriction.

Claims 51-55 depend from claim 19. Claim 19 reads "A method of producing a virus comprising: introducing into a host cell a recombinant viral expression construct comprising a polynucleotide encoding a 3' sequence of GBV-B, wherein the polynucleotide comprises 50 contiguous nucleotides from SEQ ID NO:1; and culturing said host cell under conditions permitting production of virus from said construct." The claim as amended recites SEQ ID NO:1, and claims 51-55 recite SEQ ID NO:2. The Applicants note that SEQ ID NO:2 contains all of SEQ ID NO:1, as shown in the sequence listing and described on page 6 of the specification. Because claims 51-55 incorporate the limitations of claim 19, from which they

depend, these claims are directed to nucleic acids whose structure is similar in that they both contain the newly defined 3' GBV-B sequence of SEQ ID NO:1. Hence, no additional search would be required by the Examiner for claims 51-55 should claim 19 be found allowable, because of the overlap in sequence with independent claim 19, *i.e.*, SEQ ID NO:1. Thus, if claim 19 is allowable then any additional sequence would not affect the patentability of claims 51-55, in fact claims 51-55 are drawn to a further limitation of claim 19. Applicants retain the right to have a reasonable number of species examined, should the elected species be found patentable.

In light of the foregoing, the Applicants respectfully request that the Examiner reconsider claims 51-55.

Claims 19-21, 27-33 and 56 satisfy 35 U.S.C. §112, second paragraph

Claims 19-21, 27-33 and 56 are rejected under 35 U.S.C. §112, second paragraph, as being vague and indefinite for failing to particularly point out and distinctly claim the subject matter which the application regards as the invention. As noted in the MPEP (2171) there are two separate requirements for claims under 35 U.S.C. §112, second paragraph, "If a rejection is based on 35 U.S.C. §112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention." MPEP §2171 citing *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984). The Action mailed on March 27, 2002 rejects claims 19-21 and 27-33 under 35 U.S.C. §112, second paragraph as being indefinite. However, it is unclear to the Applicants whether the Final Office Action mailed October 21, 2002 is basing the rejection of claims 19-21, 27-33, and 56 on

indefiniteness, a failure to claim what applicants regard as their invention or both. Applicants address both of these possibilities below.

Applicants propose that the pending claims 19-21, 27-33 and 56 set forth the subject matter that applicants regard as their invention and convey to one of skill in the art the scope of the claimed invention. To further clarify the pending claims and to advance prosecution Applicants have amended claims 19 and 56, herein to read:

> 19. A method of producing a ***virus*** comprising: introducing into a host cell a recombinant ***GBV-B viral expression construct*** comprising a polynucleotide encoding a ***3' terminal sequence of GBV-B***, wherein the polynucleotide comprises 50 contiguous nucleotides from SEQ ID NO:1; and culturing said host cell under conditions ***permitting production of a virus*** from said construct. (emphasis added)
>
> 56. A method of producing a GBV-B or chimeric GBV-B virus comprising: obtaining a virus produced by the method of claim 19, introducing the virus into a second host cell; and culturing said host cell under conditions permitting production of virus.

Applicants respectfully traverse the rejection.

A. Claims 19-21, 27-33 and 56 are definite

The Action argues that a "virus" *per se* cannot be produced by a 3' portion of a viral genome; an intact virus can be produced by expression of the entire viral genome only, providing that appropriate viral early proteins are available for processing; and the expression of viral genes is not the same as making or replicating virus. These issues, in light of the amended claims, are addressed below.

In regard to 35 U.S.C. §112, second paragraph, definiteness of claim language ***must*** be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one

possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP 2173). Section 2173.02 of the MPEP reads in part:

> In reviewing a claim for compliance with 35 U.S.C. §112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope. MPEP 2173.02

In light of this standard, one of ordinary skill in the art would be able to understand that the claimed invention encompasses methods for producing a virus containing GVB-B sequence in a GVB-B or a chimeric GVB-B virus as outlined in amended claims 19 and 56, particularly in light of pages 24-27 and 32-38 of the specification.

The claims, as amended herein, are directed to a "method of producing a virus." The term "virus" is well known to one of ordinary skill in the art as evinced by the definition provided in Webster's New Twentieth Century Dictionary, Unabridged, that defines "virus" as "(a) any of a group of ultramicroscopic or submicroscopic ***infective*** agents that cause various disease...viruses are capable of ***multiplying in connection with living cells*** and are variously regarded as living organisms and as complex proteins...." (Appendix C, emphasis added). The term "virus" as used in the claims and in the specification is not used contrary to its usual meaning. Thus, one of ordinary skill would understand that a "virus" as stated in the claims is an infective agent capable of multiplying in connection with living cells. One of ordinary skill in the art would realize that "producing a virus", in particular a GBV-B or chimeric virus, would include the production of an infective, replicating organism. One of ordinary skill would further understand that an infective, replicating GBV-B virus is a virus produced from expression of a RNA genome. The RNA genome of GBV-B virus contains a single reading frame that encodes a polyprotein, which is subsequently acted on by proteases to produce functional protein components of a GBV-B virus, as described in the specification at least on page 9, lines 3 to 12.

Claim 19 also recites "introducing into a host cell a recombinant GBV-B viral expression construct comprising a polynucleotide encoding a 3' terminal sequence of GBV-B" and "culturing said host cell under conditions permitting ***production of virus*** from said construct." (emphasis added). Applicants note, the specification on page 24, lines 6 to 8 describes an expression construct as any type of genetic construct containing a nucleic acid coding for a gene product in which part or all of the nucleic acid encoding sequence is capable of being transcribed (*i.e.*, in the case of GBV-B a genomic RNA encoding for a polyprotein). In addition, the 3' terminal sequence of a GVB-B virus is defined in the specification at least on pages 5, line 20 to page 6, line 2; page 9, lines 3 to 19; throughout the examples section, pages 32 to 61, and in SEQ ID NO:1. Thus, a virus produced from introducing a GBV-B viral expression construct comprising a polynucleotide encoding a 3' terminal sequence of GBV-B would be understood by one of ordinary skill in the art to include a viral genome that when expressed produces a transcript capable of producing a ***virus***.

B. Applicants claim what applicants regard as their invention.

The Action states on page 3 last line to page 4, lines 1 to 3: "Again it is impossible to determine that which applicants consider to be their invention. The pending claims do not in anyway correspond to what is taught in the specification; further resulting in an inability to determine the metes and bounds of the claims." This statement can be read only as describing a rejection under 35 U.S.C. §112, second paragraph, for failure to set forth the subject matter that the applicants regard as their invention, thus, obscuring the basis for rejection under 35 U.S.C. §112, second paragraph and rendering the Final Office Action ambiguous. In the interest of a

full and complete response to the Final Office Action mailed October 21, 2002, Applicants address this issue below.

As set forth in section 2172(I) of the MPEP regarding the requirement of 35 U.S.C. §112, second paragraph, to set forth the subject matter that applicants regard as their invention: "A rejection based on the failure to satisfy this requirement is appropriate only where applicant has stated, somewhere other than in the application as filed, that the invention is something different from what is defined by the claims. In other words, the invention set forth in the claims ***must be*** presumed, in the ***absence of evidence to the contrary***, to be that which applicants regard as their invention (MPEP 2172 citing *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971)) (emphasis added). Furthermore, agreement, or lack thereof, between the claims and the specification is properly considered only with respect to 35 U.S.C. §112, first paragraph; it is irrelevant to compliance with 35 U.S.C. §112, second paragraph (MPEP 2172(II) citing *In re Ehrreich*, 590 F.2d 902, 200 USPQ 504 (CCPA 1979)).

The Action provides no evidence, particularly in the form of contentions or admissions in briefs or remarks by the applicant that show that the claims do not correspond in scope with that which the applicant regards as applicants' invention. The content of applicants' specification can not be used as evidence that the scope of the claims is inconsistent with the subject matter which applicants regard as their invention. Thus, a rejection of claims 19-21, 27-33 and 56 under 35 U.S.C. §112, second paragraph, for failure to set forth the subject matter that applicants regard as their invention is improper and not substantiated.

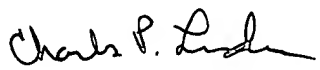
Thus, in light of the aforementioned, claims 19-21, 27-33 and 56 satisfy the requirements of 35 U.S.C. §112, second paragraph. Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 USC §112, second paragraph.

CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

The Examiner is invited to contact the undersigned patent agent at 512-536-5674 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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APPENDIX A: MARKED COPY OF THE AMENDED CLAIMS

19. (Twice amended) A method of producing a virus comprising:

introducing into a host cell a recombinant GBV-B viral expression construct comprising a polynucleotide encoding a 3' terminal sequence of GBV-B, wherein the polynucleotide comprises 50 contiguous nucleotides from SEQ ID NO:1; and

culturing said host cell under conditions permitting production of a virus from said construct.

56. (Amended) A method of producing a GBV-B or chimeric GBV-B virus comprising:

obtaining a virus produced by the method of claim 19;

introducing the virus into a second host cell; and

culturing said host cell under conditions permitting production of virus[from said construct].

APPENDIX B: COPY OF PENDING CLAIMS

19. (Twice amended) A method of producing a virus comprising:

introducing into a host cell a recombinant GBV-B viral expression construct comprising a polynucleotide encoding a 3' terminal sequence of GBV-B, wherein the polynucleotide comprises 50 contiguous nucleotides from SEQ ID NO:1; and

culturing said host cell under conditions permitting production of a virus from said construct.

20. The method of claim 19, wherein said polynucleotide comprises 100 contiguous nucleotides from SEQ ID NO:1.

21. The method of claim 20, wherein said polynucleotide comprises SEQ ID NO:1.

27. The method of claim 19, wherein said host cell is a prokaryotic cell.

28. The method of claim 19, wherein said host cell is a eukaryotic cell.

29. The method of claim 28, wherein said host cell is in an animal.

30. The method of claim 19, wherein said polynucleotide comprises recombinant RNA.

31. The method of claim 19, wherein said polynucleotide comprises recombinant DNA.

32. The method of claim 19, further comprising the step of isolating virus from said host cell.

33. The method of claim 32, wherein said virus is purified to homogeneity.

56. (Amended) A method of producing a GBV-B or chimeric GBV-B virus comprising:

obtaining a virus produced by the method of claim 19;

introducing the virus into a second host cell; and

culturing said host cell under conditions permitting production of virus.

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vī′rŭs, *n.* [L., poison.]

1. venom, as of a snake.

2. (a) any of a group of ultramicroscopic or submicroscopic infective agents that cause various diseases, as smallpox: viruses are capable of multiplying in connection with living cells and are variously regarded as living organisms and as complex proteins; (b) specifically, a filtrable virus; (c) the exudation from the vesicles of cowpox, used as a vaccine for smallpox.

3. that which corrupts or poisons the mind or character; evil or harmful influence.